UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,634	01/20/2004	Gregory E. Sancoff	D0188.70165US02	8269

23628 7590 12/23/2009

WOLF GREENFIELD & SACKS, P.C.
600 ATLANTIC AVENUE
BOSTON, MA 02210-2206

EXAMINER	
YABUT, DIANE D	
ART UNIT	**PAPER NUMBER**
3734	

MAIL DATE	DELIVERY MODE
12/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/760,634	SANCOFF ET AL.	
	Examiner	Art Unit	
	DIANE YABUT	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/19/2009 has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 7-16, 18-23, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Atala** (U.S. Patent No. **5,571,119**) in view of **Mericle** (U.S. Patent No. **5,752,964**).

Claims 7, 10, 12, 14-15, 18, 21, and 62: Atala discloses a suturing instrument comprising a handle **72**, a shaft **66** extending from the handle, the shaft having a proximal end near the handle and a distal end opposite the proximal end, the distal end of the shaft having an opening **93** and a passageway **92** (semi-circular portion of needle

90) constructed and arranged to carry a suture wire **86** to the opening and to plastically deform the suture wire as the suture wire moves through the passageway to cause the suture wire to form a wire suture loop as the suture wire is extended from the opening in the distal end of the shaft, the passageway and the opening being arranged so that the suture wire extends substantially in a distal direction upon exiting the opening and may loop back to the distal end of the shaft without requiring additional contact with the instrument, a wire drive **88** adapted to move the suture wire in the passageway, and a cutter adapted to cut the suture wire at a location near the distal end of the shaft.

It is noted that the semi-circular passageway **92** of Atala is adapted to form a wire suture loop or a curved suture, given that the suture material is a (plastically) deformable wire material and is properly sized, which Atala acknowledges may be modified (col. 9, lines 46-52).

Also, regarding Claim 62, the steps of driving deformable suture wire through a passageway in a suturing instrument having a distal end, bending the suture wire in the passageway to form a suture wire loop with suture wire that exits the distal end, the suture wire loop formed without requiring further contact of the instrument to form an annular fastener with the suture wire after the suture wire extends from the distal end of the suturing instrument, and cutting the suture wire to free the suture wire loop from the instrument encompass the same invention of Claim 7, and therefore Atala's device reads on these limitations (Figures 7-9 and col. 5, lines 41-55, col. 7, lines 51-67, col. 9, lines 43-65).

Atala does not expressly disclose that the cutter move into the instrument to free the wire suture loop or annular fastener from the instrument, or a cutter including a cutting surface, or bar, adapted to move axially along a shaft of an instrument to cut a suture wire.

Mericle teaches a suturing instrument with a cutter **19** including a cutting surface, or bar, adapted to move axially along a shaft of an instrument to cut the suture wire, which eliminates the need for another instrument such as scissors to cut excess suture material (Figure 4, col. 4, lines 1-28, col. 2, lines 45-51). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a cutter with a cutting surface to move axially along the shaft **94** of Atala to cooperate with the passageway **92**, as taught by Mericle, in order to eliminate the need for a separate cutting instrument and offer multi-functionality and simplicity for the surgeon.

Claim 8: Atala discloses the wire drive **88** moving the suture wire **86** through the passageway, a free end of the suture wire exiting the opening in the distal end and following an arcuate, or curved, path **92** whereby the free end may loop or lead back toward the instrument (Figures 7-9, col. 9, lines 43-65).

Claim 9: Atala discloses the wire drive **88** being adapted to move the suture wire **86** with force sufficient to cause a free end of the suture wire to penetrate tissue (Figures 7-9, col. 9, lines 43-65).

Claim 11: Atala discloses the handle having a manually operable actuator adapted to actuate the wire drive (Figures 7-9, col. 7, lines 51-67).

Claim 13: Atala discloses the suturing instrument being adapted to form the wire suture loop at an extreme axial end of the shaft (Figures 7-9).

Claim 16: Atala discloses the wire drive being adapted to move the suture wire in an axial direction within the shaft (Figures 7-9, col. 9, lines 43-65).

Claim 19: Atala discloses a continuous length of suture wire **86**, wherein the instrument is adapted to form a plurality of wire suture loops from the continuous length of suture wire (Figures 7-9).

Claim 20: Atala discloses the suturing instrument adapted for use in a minimally invasive surgical procedure (col. 3, lines 30-35).

Claim 22: Atala discloses the distal end of the shaft including an angled end face (Figures 8-9).

Claim 23: Atala discloses the suturing instrument arranged to form a wire suture loop in tissue by positioning the angled end face adjacent the tissue and driving the suture wire through the passageway such that a free end of the suture wire may penetrate the tissue and follows a loop-like trajectory (Figures 7-9).

Claim 31: Atala discloses the suturing instrument adapted to form an approximately circular wire suture loop by suture wire that is driven out of the opening in the distal end (Figures 7-9).

3. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Atala** (U.S. Patent No. **5,571,119**) and **Mericle** (U.S. Patent No. **5,752,964**), as applied to Claim 7 above, and further in view of **Gordon** (U.S. Patent No. **5,741,277**).

Claim 17: Atala and Mericle disclose the claimed device, as discussed in paragraph 2 above, except for the passageway including an "S" shaped portion that is adapted to deform the suture wire moving through the "S" shaped portion.

Gordon teaches a suturing instrument with a passageway including an "S" shaped portion that is adapted to deform a suture wire moving through the "S" shaped portion (Figures 39, 41A-41C, and col. 26, lines 57-67, col. 27, lines 1-14). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Atala and Mericle by providing an "S" shaped portion in the passageway, as taught by Gordon, since it was known in the art that convoluted channels in suturing instruments are used to facilitate forming loops in sutures so as to eliminate the need for a separate looping, knotting instrument.

4. Claims 24-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Atala** (U.S. Patent No. **5,571,119**) in view of **Mericle** (U.S. Patent No. **5,752,964**) and **Gordon** (U.S. Patent No. **5,741,277**).

Claims 24-42: Atala and Mericle disclose the claimed device, as discussed in paragraph 2 above, except for the passageway including a first radius of curvature and a second lateral radius of curvature in a different direction than the first radius of curvature which carries a suture wire.

Gordon teaches a suturing instrument with a passageway including a first radius of curvature (near **534**) and a second lateral radius of curvature (near **562**) in a different direction than the first radius of curvature which carries a suture wire. (Figures 39, 41A-

41C, and col. 26, lines 57-67, col. 27, lines 1-14). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Atala and Mericle by providing a first radius of curvature and a second lateral radius of curvature in a different direction than the first radius of curvature which carries a suture wire in the passageway, as taught by Gordon, since it was known in the art that convoluted channels in suturing instruments are used to further facilitate forming loops in sutures so as to eliminate the need for a separate looping, knotting instrument.

5. Claims 43-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al., hereinafter "**Makower**" (U.S. Patent No. **6,090,063**) in view of **Gordon** (U.S. Patent No. **5,741,277**).

Claims 43-61: Makower discloses a handle **7**, a shaft **6** with an angled end face extending from the handle having a distal end with an opening and a passageway adapted to carry a suture wire to the opening, a wire drive **9** adapted to move a suture wire axially in the passageway, and a cutter or cutting bar **213** that moves axially along the shaft to cut the suture wire at a location near the distal end of the shaft to free the wire from the instrument. (Figures 1 and 27A-C; col. 7, lines 51-67 and col. 17, lines 1-36). A suture wire may extend in a generally distal direction upon exiting the opening, and depending on the type of wire, the wire drive may move the suture wire with force sufficient to penetrate tissue.

Although Makower teaches including or forming a part of the passageway for the suture as seen in Figure 27B, Makower does not expressly disclose the passageway

having a curved or "S" shaped portion, or convex and concave portions arranged so that the suture wire moving through and exiting the opening forms suture wire loops.

Gordon teaches a suturing instrument with a passageway including an “S” shaped portion that is adapted to deform a suture wire moving through the “S” shaped portion (Figures 39, 41A-41C, and col. 26, lines 57-67, col. 27, lines 1-14). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Makower by providing an “S” shaped portion in the passageway, as taught by Gordon, since it was known in the art that convoluted channels in suturing instruments are used to facilitate forming loops in sutures so as to eliminate the need for an additional looping, knotting instrument and to securely attach to tissue. Also, it would have been obvious to one of ordinary skill in the art to provide a cutter bar adapted to cut the suture wire at a location between convex and concave portions, since applicant since applicant has not disclosed that cutting specifically between the convex and concave portions solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with this configuration.

Response to Arguments

6. Applicant's arguments filed 10/19/2009 have been fully considered but they are not persuasive.

7. Applicant argues that the device of Atala already includes a cutter (col. 5, lines 46-48) and therefore it would be unobvious to modify Atala with the cutter bar of Mericle. However, the examiner asserts that Atala is referring to “an alternative

embodiment" wherein the notch **16** may include an interior or exterior cutting edge, but does not necessarily have this feature since "[f]urther embodiments that do not depart from the essence of the present invention will be apparent to those skilled in the art of surgical device design and surgical procedures" (col. 5, lines 53-56), which may include an actuatable cutter mechanism that allows the user to selectively cut suture, as taught by Mericle, and therefore in addition to driving a suture wire, it would offer multi-functionality and eliminate the need for a separate cutting instrument. Therefore it would have been obvious to provide a cutter to move axially along the shaft **94** of Atala to cooperate with the passageway **92**, as taught by Mericle, in order to eliminate the need for a separate cutting instrument and offer multi-functionality and simplicity for the surgeon.

8. Applicant also generally argues that neither Atala nor Gordon discloses a device that would necessarily form a suture wire loop, and there is no disclosure to support mere speculation that the passageways of the device of Atala or Gordon would form a suture wire loop. Although there is no explicit disclosure that a suture wire loop is formed, the examiner asserts that the passageway **92** of Atala and the passageway of Gordon in Figures 41A-41C both have bends and turns and curvatures that would impart deflection on a properly sized, deformable wire material, and therefore the passageways provide a sufficient structure for a driven deformable suture wire to bend and curve or loop when exiting the passageway.

9. Applicant's arguments with respect to claims 24-42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734